



DEPARTMENT OF HEALTH AND HUMAN SERVICES

FBI: 1119939



95171d  
Food and Drug Administration  
Baltimore District Office  
6000 Metro Drive  
Suite 101  
Baltimore, MD 21215-3215  
Telephone: (410) 779-5454

05-BLT-06

December 23, 2004

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Dewitt D. Park, Manager and Co-Owner  
C/O Wingate Seafood, L.L.C.  
D.B.A. Tideland Seafood  
2102 Wingate-Bishops Head Road  
Wingate, Maryland 21675

Dear Mr. Park:

The Food and Drug Administration (FDA) conducted an inspection of your crabmeat processing facility located at 2102 Wingate-Bishops Head Road, Wingate, Maryland 21675, on September 21, 22, 23, and 24, 2004. Your facility was inspected to determine compliance with the Good Manufacturing Practice (GMP) Regulations, Title 21, Code of Federal Regulations (CFR), Part 110 and the Fish and Fishery Products regulations (Seafood HACCP), Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). The deviations cited during your inspection cause the seafood you process to be adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (FD&C Act). The deviations are as follows:

Specifically more than 100 live flying insects we observed and photographed inside your crabmeat picking and packing rooms. These insects were observed landing on food contact surfaces including crabmeat packing cups, crabmeat packing lids, crabmeat pickers' hand towels, crabmeat pickers' work tables, the cooked crab shovel and the cooked crab distribution basket. In addition, these insects were observed landing directly on cooked crabs and picked crabmeat. Insects may serve as vectors for diseases of humans, particularly in the case of a ready-to-eat product that may not be heated to destroy possible contamination prior to consumption.

In addition, you failed to adequately monitor sanitation conditions and practices during processing so as to comply with 21 CFR 123.11(b). Your firm did not monitor two (2) of the eight (8) areas of sanitation with sufficient frequency to ensure control for your high-risk, ready-to-eat seafood products as follows:

1. Your firm failed to maintain sanitation records monitoring the exclusion of pests from the food plant and failed to take corrective action, such as installing adequate screening, to prevent their entry into food processing areas. [21 CFR 123.11(b)(8), 21 CFR 123.11(c) and 21 CFR 123.9]

2. You failed to maintain hand washing, hand sanitizing, and toilet facilities, as evidenced by the absence of soap, a hand drying device, and toilet tissue in the toilet facilities. [21 CFR 123.11(b)(4)]

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations. You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice, including seizure, injunction, and/or prosecution.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed with 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Attention: Elizabeth A. Laudig, Compliance Officer, 6000 Metro Drive, Suite 101, Baltimore, MD 21215. If you have any questions regarding this letter or implementation of the seafood HACCP regulations, you may contact Elizabeth A. Laudig at 410-779-5441.

Sincerely,



Roberta F. Wagner  
Acting Director, Baltimore District

Cc: State Department of Health and Mental Hygiene  
Attn: Arlene Stephenson, Acting Secretary  
201 W. Preston Street  
Baltimore, MD 21201